

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

WELCH ALLYN, INC.,

Plaintiff,

-vs-

**OBP CORPORATION and OBP MEDICAL
INC.,**

Defendants.

Civil Action No.
5:14-cv-01122-TJM-DEP

DECLARATION OF SCOTT G. SPANFELNER

Scott G. Spanfelner hereby declares as follows:

1. I work at the plaintiff, Welch Allyn, Inc. ("Welch Allyn") as Director of Enterprise Program Management.
2. I make this Declaration based upon my personal knowledge and my review of records and information currently available. If called to testify in this action, the following would constitute a portion of my direct testimony.

Background

3. I am a mechanical engineer with over twenty-five (25) years of experience spanning the fields of biomedical engineering, materials science, optics, and electro-mechanical design. I am also a former member of the American Society of Mechanical Engineers.

4. I graduated from the Rochester Institute of Technology in 1987 with a Bachelor of Science in Mechanical Engineering and have since then worked in research and development as a mechanical and manufacturing engineer, as well as Manager of the Strategic Business Units of

Advanced Manufacturing, Product Development, Women's Health and Medical Lighting. My work experience includes designing and testing medical diagnostic instruments, developing manufacturing processes, organic and inorganic business development, marketing, and general corporate program management. Most recently, as Director of Enterprise Program Management, I am responsible for the program management of a variety of corporate initiatives in operations, business development and product development including development of products for automated vision screening and wireless temperature measurement.

The Art Involved in the '175 Patent and Persons of Ordinary Skill in the Art

5. The art involved in the '175 Patent is the design, manufacture or utilization of vaginal specula, which involve mechanical, electrical and optical elements. Given the different technical disciplines involved, the design of vaginal specula is an interdisciplinary and collaborative effort. The scope of knowledge and skills available to persons of ordinary skill working in this art at the time of the invention at issue in this case would have included, in addition to their own educational background and training, working knowledge about the types of uses made of vaginal specula by physicians, obstetricians, gynecologists, and other medical practitioners. Thus, persons having ordinary skill in the art at the time of the invention would have included engineers working collaboratively and having among them at least a bachelor's degree in biomedical, technical, mechanical, optical and/or electrical engineering, several years of experience in designing, testing or manufacturing diagnostic medical devices, and several years of experience working in the healthcare industry.

The Invention

6. "Vaginal specula are . . . used in the field of diagnostic medicine for purposes of examining the cervix of a female patient. A typical vaginal speculum includes an upper blade

member and a lower blade member that are operated upon to open and close by means of an articulation mechanism in order to dilate the vaginal cavity of the patient.” (U.S. Patent No. 8,435,175 (the “175 Patent”), Col. 1, lines 28-34.) To effectively examine inside the vaginal cavity of a patient, a light source is often used in conjunction with vaginal specula to provide sufficient illumination of the examination area. (See *id.*, at Col. 1, lines 35-52.) However, medical practitioners have encountered significant difficulty in doing so effectively.

7. For example, some specula were used with an illumination assembly in which a light source was powered using a tethered power cable. However, “there are occasions in which such assemblies make examination impractical to perform such as, for example, instances in which the patient is bed-ridden. In these situations, the corded portion of the speculum apparatus can become an impediment to examining a patient. In addition, the use of corded illumination assemblies requires a non-portable (e.g., AC) power supply to be present in the examination area, making field examinations difficult. Still further, corded assemblies can become tangled or become a source of dirt or other contamination, requiring frequent cleaning between examinations.” (See *id.*, at Col. 2, lines 17-29.)

8. In addition, light sources used with specula have caused so-called “hot” spots in which the light source “produces back reflection of light to the eye of the user . . . [which] produces considerable amounts of glare, thereby impairing the effectiveness of an examination.” (See *id.*, at Col. 1, lines 53-63.) Moreover, light sources positioned within the specula can extend “into the lower field of view of the user (e.g., the physician), creating obstruction of the target.” (See *id.*, at Col. 1, lines 64-67.) Relatedly, “body fluids expelled from examination are often trapped by the [light source], producing a contamination issue as well as impairing the efficiency of examination

given the effect on light transmission of a buildup of fluids against the light-emitting surface of the light pipe.” (*See id.*, at Col. 2, lines 11-16.)

9. In 2002, an inter-disciplinary team of Welch Allyn mechanical, electrical and optical engineers started to work on various solutions to the problems associated with illuminated vaginal specula. At that time, LEDs typically were not used as illumination sources in medical products, including vaginal specula. In fact, “the incorporation of such light sources in portable illumination systems for vaginal specula [had] been discouraged in the field due to inefficiencies in power conversion and illumination output,” and were “presently unavailable for use in such apparatus.” (*See id.*, at Col. 2, lines 30-38.) Despite this, the Welch Allyn team explored a number of designs using LED technology.

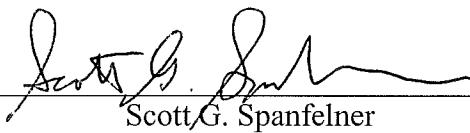
10. Among the novel ideas conceived by Welch Allyn was the use of a disposable cartridge that included an LED and batteries and was located either in the upper or lower blade of the speculum. The cartridge could be removable and would either turn on automatically when inserted into one of the blades, or it could be turned on using a switch, such as a pull out activation tab. Welch Allyn also conceived using a removable light pipe or prism that could be used to transmit light from an LED to the examination area of the patient. Contemporaneous documents and records kept by Welch Allyn in the ordinary course of its business (which were, upon information and belief, produced to OBP during discovery in this case) evidence the fact that these ideas were conceived and reduced to practice no later than August 29, 2002 by which time a working prototype embodying these ideas had been constructed.

11. These ideas are disclosed in detail in the ’175 Patent, including, among other places, Figures 23, 24 and 35, and the specification’s accompanying discussion of those figures. These ideas represented a true breakthrough in the design of vaginal specula. For the first time, it was

understood how to make a fully disposable illuminated vaginal speculum without a tethered power cord that also helped reduce “hot” spots, obstructed views, and contamination of the light source, all while utilizing LED technology that, prior to the invention disclosed in the ’175 Patent, was thought to be unsuitable for use in vaginal specula.

In accordance with 28 U.S.C. § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: May 28, 2015



Scott G. Spanfelner